K041343

# 510(k) SUMMARY

JUN 1 6 2004

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, PA 17405-0872
P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: May 17, 2004

TRADE OR PROPRIETARY NAME: XENO® NM Light Cured Dental Adhesive

CLASSIFICATION NAME: Resin tooth bonding agent (872.3200)

PREDICATE DEVICES: Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive K982394

DEVICE DESCRIPTION:

The XENO® NM Light Cured Dental Adhesive is a one-component light cure self-etching and self-priming dental adhesive designed to bond composite materials and compomers to enamel and dentin as well as to metals and ceramic.

XENO® NM Light Cured Dental Adhesive combines acid etching, priming and adhesive in a single bottle.

INTENDED USE:

- Direct composite and compomer restorations.
- Veneer
- Composite, ceramic and metal repairs.
- Cavity varnish for use with fresh amalgam

TECHNOLOGICAL CHARACTERISTICS:

All of the components found in XENO® NM Light Cured Dental Adhesive have been used in legally marketed devices.

XENO® NM Light Cured Dental Adhesive final formulation was evaluated for biocompatibility for genotoxicity, cytotoxicity, and sensitivity and found acceptable.

We believe that the prior use of the components of XENO® NM Light Cured Dental Adhesive in legally marketed devices, the biocompatibility data provided, and the performance data provided support the safety and effectiveness of XENO® NM Light Cured Dental Adhesive for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2004

Dentsply International
Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404-0872

Re: K041343
Trade/Device Name: XENO® NM Light Cured Dental Adhesive
Regulation Number: 872.3200
Regulation Name: Resin tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: May 17, 2004
Received: May 20, 2004

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K041343

Device Name: **XENO® NM Light Cured Dental Adhesive**

Indications for Use:

XENO® NM Light Cured Dental Adhesive is indicated for:

- Direct composite and compomer restorations for all cavity classes in anterior and posterior teeth
- Veneers
- Composite, ceramic and metal repairs
- Cavity varnish for use with fresh amalgam

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control. Dental Devices

510(k) Number: K041343